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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,909	09/18/2001	Marc Pelletier	40853-01-5028-01	8433

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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 12/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/955,909

Applicant(s)

PELLETIER ET AL.

Examiner

Francisco C Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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**DETAILED ACTION**

The preliminary amendment filed September 18, 2001, has been received and entered.

Claims 37-46 have been cancelled.

Claims 1-36 are pending and are examined on the merits.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the preparation of sialyl- 2,3- -galactosides from starting materials containing sialyloligosaccharides, does not reasonably provide enablement for the preparation of any and all sialyloligosaccharides from any and all dairy products, as currently recited in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

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Specifically, the claim-designated enzyme has a very specific activity. It transfers, in a transglycosylation-type reaction, sialic acid from sialyloligosaccharides (preferably 2,3 linked sialic acid) to  $\beta$ -galactosides, to yield sialyl- $\alpha$ -2,3- $\beta$ -galactosides. See, e.g., Vandekerckhove et al (Glycobiology 2(6):541-548 (1992)). However, the cited claims all encompass processes wherein either the starting material may contain none of the known donor substrates for the enzyme, or where the product of the enzyme's action may be a product not producible by the enzyme's known action. In view of the fact that applicant has not provided any guidance in varying the known action of the trans-sialidase enzyme, combined with the enzyme's known relatively strict specificity, the skilled artisan would expect to have to experiment unduly to practice the full scope of the subject matter encompassed by the claims. Thus, a holding of non-enablement, with the exception of the preparation of sialyl  $\alpha$ -2,3- $\beta$ -galactosides from starting materials containing sialyloligosaccharides, is proper.

The following is a quotation of the second paragraph of 35

U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, it is not clear what subject matter is encompassed by the recitation "dairy source." It is respectfully submitted that the metes and bounds of the subject matter encompassed by the recitation are not clear. For example, it is respectfully submitted that the recitation encompasses contacting cows or goats with the claim-designated enzyme, a situation the skilled artisan would not expect to produce the desired product.

Also, the claims are incomplete, and therefore indefinite, because it is not clear from the current claim language how the trans-sialidase relates to the production of the sialyloligosaccharides. That is, it is not clear what compound present in the starting material the enzyme is acting on to yield sialyloligosaccharides. Moreover, many dairy products, including the claim-designated cheese processing waste already contain sialyloligosaccharides. Thus, when taken in light of the prior art, the claims are confusing because they recite

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preparing a compound from a raw starting material which already contains the compound.

The Markush group in claim 11 is confusing because it is not clear how lactose differs from any of the other lactoses recited in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 36 is rejected under 35 U.S.C. 102(b) as being anticipated by Vandekerckhove et al (Glycobiology 2(6):541-548 (1992)).

Vandekerckhove discloses the preparation of 2,3-sialyllactose by contacting lactose with 2,3-trans-sialidase in the presence of various sialyloligosaccharides. See, e.g., abstract, page 542 (Table 1). A holding of anticipation is clearly proper.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vandekerckhove et al (Glycobiology 2(6):541-548 (1992)) in view of Brian et al (U.S. Pat. 5,575,916) and Ito et al (U.S. Pat. 5,409,817).

As discussed above with respect to § 102(b), Vandekerckhove discloses the preparation of 2,3-sialyllactose by contacting lactose with 2,3-trans-sialidase in the presence of various sialyloligosaccharides. Vandekerckhove differs from the cited claims in that Vandekerckhove does not use dairy products as

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substrate for the enzyme. However, Brian et al disclose that dairy products, including cheese processing waste, contain sialyloligosaccharides which are substrates for the 2,3-trans-sialidase. Thus, the artisan of ordinary skill at the time of applicant's invention would have deemed obvious that one could have prepared sialyloligosaccharides by the claimed method of contacting a cheese processing waste stream with an 2,3-trans-sialidase. Motivation for such a process clearly would have been derived from the known utility of the resulting product, such as the presence of the 2,3-sialyllactose produced by the enzyme's action in sialyl Lewis x, disclosed for example in the Ito patent. Motivation for using the claimed recovery steps would have been obvious in view of the fact that Brian discloses that the claimed recovery steps were suitable for the recovery of sialyloligosaccharides from products such as cheese waste streams. Motivation for using a recombinantly produced enzyme would have been derived from the fact that the artisan of ordinary would have expected a recombinantly produced enzyme to have functioned at least equivalently to the enzyme produced from the natural source. A holding of obviousness over the cited claims is therefore proper.

In sum, these claims fail to be patentably distinguishable over the state of the art discussed above and cited on the



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enclosed PTO-1449 and/or PTO-892. Therefore, the claims are properly rejected under 35 U.S.C. § 103(a).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).


Claims 1-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,323,008 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims, though broader than the patented claims, clearly recite subject matter which greatly overlaps the patented subject matter. A terminal disclaimer is clearly required.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Francisco C Prats  
Primary Examiner  
Art Unit 1651

FCP  
December 9, 2002